

# Japanese Pharmaceutical Excipients

**Japanese Pharmaceutical Excipients** Japanese pharmaceutical excipients are vital components in the formulation of medicines produced in Japan, contributing to the stability, bioavailability, manufacturability, and overall efficacy of pharmaceutical products. As Japan is renowned for its advanced pharmaceutical industry and strict regulatory standards, Japanese pharmaceutical excipients are highly regulated, ensuring high quality and safety. This comprehensive guide explores the key aspects of Japanese pharmaceutical excipients, including their types, regulatory environment, manufacturing practices, and notable market trends.

--- **Understanding Pharmaceutical Excipients** Pharmaceutical excipients are inactive substances formulated alongside the active pharmaceutical ingredient (API) to aid in the manufacturing process, protect the drug from degradation, enhance stability, or improve patient acceptability. They are not intended to exert therapeutic effects but are crucial for the drug's performance. Common functions of excipients include:

- Bind agents to hold tablets together
- Fillers or diluents to add volume
- Disintegrants to facilitate tablet breakup
- Lubricants to improve flow during manufacturing
- Coatings to control drug release or mask taste
- Preservatives to inhibit microbial growth

--- **Types of Japanese Pharmaceutical Excipients** The Japanese pharmaceutical industry employs a wide variety of excipients, many of which are sourced domestically or imported under strict quality control. Below are the main categories:

**Binders and Fillers**

- Microcrystalline Cellulose (MCC): Widely used for its excellent binding properties.
- Lactose Monohydrate: A common filler and diluent.
- Starch and Starch Derivatives: Used for binding and disintegration.
- Calcium Phosphate: An inert filler with good compressibility.

**Disintegrants**

- Croscarmellose Sodium: Swells in the presence of water to disintegrate tablets.
- Sodium Starch Glycolate: Enhances disintegration.

**Lubricants and Glidants**

- Magnesium Stearate: A standard lubricant.
- Colloidal Silica: Improves powder flowability.

**Coatings and Film-Formers**

- Hydroxypropyl Methylcellulose (HPMC): Used for controlled-release coatings.
- Polyvinyl Alcohol (PVA): For film coatings.

**Preservatives and Antioxidants**

- Sodium Benzoate: Preserves aqueous formulations.
- Ascorbic Acid: An antioxidant.

**Specialized Excipients**

- Beta-Cyclodextrin: Enhances solubility of poorly soluble drugs.
- Gelling Agents (e.g., Pectin): Used in topical formulations.

--- **Regulatory Landscape for Japanese Pharmaceutical Excipients** Japan's pharmaceutical excipient market operates under a rigorous regulatory framework designed to ensure safety, efficacy, and quality. The key regulatory bodies include:

- Pharmaceuticals and Medical Devices Agency (PMDA): Responsible for approval and oversight.
- Ministry of Health, Labour and Welfare (MHLW): Establishes standards and guidelines.

Regulatory standards and guidelines include:

- Good Manufacturing Practices (GMP) compliance
- Registration and approval processes for excipient manufacturing
- Specifications for purity, stability, and safety

The Japanese Pharmacopoeia (JP) provides official monographs and standards for pharmaceutical excipients used domestically, aligning with international standards such as the United States Pharmacopeia (USP) and European Pharmacopoeia.

(EP). --- Manufacturing Practices and Quality Assurance Manufacturers of Japanese pharmaceutical excipients adhere to strict quality protocols to meet both domestic and international standards. Key aspects include: - GMP Compliance: Ensures consistent quality and safety across batches. - Raw Material Control: Sourcing high-quality raw materials with traceability. - Analytical Testing: Rigorous testing for contaminants, residual solvents, microbial limits, and physical properties. - Stability Testing: Confirming excipient stability under various storage conditions. - Documentation and Certification: Providing Certificates of Analysis (CoA) and compliance reports. Leading Japanese excipient manufacturers invest heavily in R&D to develop innovative excipients that meet evolving pharmaceutical needs, including sustained-release formulations, taste- masking, and targeted delivery systems. ---

### 3 Market Trends and Innovations in Japanese Pharmaceutical Excipients

The Japanese pharmaceutical excipient market is characterized by steady growth driven by advancements in drug delivery technologies and regulatory pressures. Key trends include:

1. Focus on Safety and Natural Excipients - Increasing demand for excipients derived from natural sources to meet consumer preferences and regulatory scrutiny. - Development of biodegradable and environmentally friendly excipients.
2. Innovation in Controlled-Release and Targeted Delivery - Use of novel polymers and coating materials to enable precise drug release profiles. - Incorporation of cyclodextrins and other solubilizers to improve bioavailability.
3. Expansion of Biopharmaceutical Excipients - Growing use of excipients compatible with biologics and biosimilars. - Emphasis on excipients that support stability and delivery of complex molecules.
4. Regulatory Advancements and Global Standardization - Alignment with international pharmacopoeias to facilitate export. - Adoption of stricter quality standards in response to global markets.
5. Environmental Sustainability - Development of eco-friendly manufacturing processes. - Use of renewable raw materials.

--- Key Japanese Excipients Manufacturers Several Japanese companies are leading the market in excipient production, including: - Kao Corporation: Known for high-quality film coatings and disintegrants. - Kikkoman Corporation: Developing specialty excipients, including cyclodextrins. - Nacalai Tesque: Focuses on research-grade excipients and reagents. - Pioway Pharmaceutical: Innovating in sustained-release and bio-compatible excipients. These companies emphasize research, compliance, and innovation to meet domestic and international pharmaceutical industry demands. ---

### 4 Challenges and Future Outlook

While Japanese pharmaceutical excipients enjoy a reputation for quality, the industry faces challenges such as: - Regulatory complexities in global markets. - Rising raw material costs impacting pricing. - Need for innovation to keep pace with advanced drug delivery systems. - Environmental regulations requiring sustainable manufacturing. Future prospects include increased adoption of biodegradable and natural excipients, integration of nanotechnology, and expanded use in biopharmaceuticals. Japan's commitment to innovation and quality positions its excipient industry for continued growth and global influence. ---

### Conclusion

Japanese pharmaceutical excipients are integral to the country's robust pharmaceutical industry, characterized by high quality standards, innovative formulations, and strict regulatory oversight. From traditional binders and fillers to cutting-edge controlled-release polymers, these excipients enhance drug efficacy and patient compliance. As the industry evolves, Japanese excipient manufacturers will likely lead the way in sustainable, biocompatible, and technologically advanced excipients, reinforcing Japan's position as a global leader in pharmaceutical excipient manufacturing. ---

Keywords

for SEO Optimization: - Japanese pharmaceutical excipients - Pharmaceutical excipients Japan - Japan excipient market - Innovative excipients Japan - Regulatory standards Japanese pharmaceuticals - Biodegradable pharmaceutical excipients - Controlled-release excipients Japan - Japanese excipient manufacturers - Quality standards in Japan pharma - Excipient trends Japan QuestionAnswer What are the most commonly used pharmaceutical excipients in Japanese medicines? In Japan, commonly used pharmaceutical excipients include lactose, microcrystalline cellulose, magnesium stearate, sodium starch glycolate, and hydroxypropyl methylcellulose, which are employed for tablet formulation, disintegration, and stability. How does Japan regulate the safety of pharmaceutical excipients? Japan's Ministry of Health, Labour and Welfare (MHLW) oversees the regulation of pharmaceutical excipients through the Pharmaceuticals and Medical Devices Act, ensuring they meet safety, quality, and efficacy standards based on the Japanese Pharmacopoeia and international guidelines. Are there any specific excipients unique to Japanese pharmaceutical formulations? While most excipients are globally used, Japan sometimes utilizes locally sourced or traditional excipients, such as specific starches or plant-derived components, tailored to regional preferences and regulatory standards. 5 What recent trends are observed in the development of pharmaceutical excipients in Japan? Recent trends include the development of excipients with improved bioavailability, stability, and compatibility, as well as the adoption of excipients that facilitate the manufacturing of high-dose or controlled-release formulations. How are natural and plant-based excipients viewed in the Japanese pharmaceutical industry? Natural and plant-based excipients are increasingly preferred in Japan due to consumer demand for 'green' medicines, emphasizing safety, biocompatibility, and traditional usage, while meeting strict regulatory criteria. What role do excipients play in the formulation of Japanese traditional medicines (Kampo)? In Kampo medicines, excipients such as starches and binders are used to enhance stability, facilitate manufacturing, and improve the delivery of active herbal ingredients, aligning with traditional practices and modern pharmaceutical standards. Are there any upcoming regulatory changes affecting pharmaceutical excipients in Japan? Japan is continuously updating its regulations to align with international standards, including stricter control over impurity profiles, allergenicity assessments, and the approval process for novel excipients, aiming to enhance safety and innovation in pharmaceutical formulations. Japanese pharmaceutical excipients have garnered significant attention within the global pharmaceutical industry due to their high standards of quality, safety, and innovation. As Japan continues to be a leader in pharmaceutical research and development, the role of excipients—substances formulated alongside the active pharmaceutical ingredient (API) to facilitate manufacturing, stability, and bioavailability—has become increasingly prominent. This article offers a comprehensive analysis of Japanese pharmaceutical excipients, exploring their types, regulatory landscape, manufacturing practices, innovations, and the impact they have on global medicine development. --- Understanding Pharmaceutical Excipients: An Overview Pharmaceutical excipients are inert substances that serve various functions in drug formulations, including aiding in the manufacturing process, improving drug stability, controlling drug release, and enhancing patient acceptability. Though they are considered inert, excipients are critical to the efficacy and safety of medications. Their selection depends on multiple factors such as compatibility with APIs, stability profiles, and route of administration. In Japan, excipients

are subject to rigorous quality standards aligned with both domestic regulations and international guidelines, reflecting the country's commitment to high pharmaceutical standards. The Japanese pharmaceutical excipient market is characterized by meticulous manufacturing processes, innovative formulations, and a focus on safety. --- Japanese Pharmaceutical Excipients

### 6 Types of Pharmaceutical Excipients in Japan

Japanese pharmaceutical excipients encompass a broad spectrum of substances, each serving specific roles in drug formulation. The main categories include:

- 1. Binders and Fillers** These excipients provide cohesion to tablet formulations and contribute to the bulk of the dosage form. Common binders include microcrystalline cellulose, starch derivatives, and polyvinylpyrrolidone (PVP). Fillers such as lactose monohydrate and dibasic calcium phosphate are prevalent in Japanese formulations, chosen for their inertness and compatibility.
- 2. Disintegrants** Disintegrants facilitate the breakup of tablets upon contact with bodily fluids, ensuring rapid drug release. In Japan, sodium starch glycolate and croscarmellose sodium are favored for their efficacy and safety profiles.
- 3. Lubricants and Glidants** These improve the flow properties of powders and reduce tablet sticking during compression. Magnesium stearate and colloidal silica are common, with Japanese manufacturers often using high-purity grades to meet strict quality criteria.
- 4. Preservatives and Antioxidants** Used mainly in liquid formulations, preservatives like parabens and antioxidants such as ascorbic acid are selected with attention to biocompatibility and stability.
- 5. Coatings and Film-Forming Agents** Enteric coatings and film coatings improve stability and mask taste. Japanese excipients include hydroxypropyl methylcellulose (HPMC) and methacrylate derivatives, ensuring controlled release and protection from environmental factors.
- 6. Solubilizers and Surfactants** These enhance the solubility of poorly soluble drugs. Polysorbates and sodium lauryl sulfate are examples used in Japanese formulations.

--- Regulatory Framework for Excipients in Japan

The regulation of pharmaceutical excipients in Japan is governed primarily by the Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA). Ensuring excipient safety and quality involves a rigorous approval process, aligned with international standards such as those established by the International Conference on Harmonisation (ICH).

### Key Regulatory Aspects

- **Approval and Registration:** Excipients must be approved prior to use in drug products. Manufacturers submit dossiers demonstrating the excipient's safety, manufacturing process, and quality control measures.
- **Good Manufacturing Practice (GMP):** Excipients are produced under GMP conditions, emphasizing purity, consistent quality, and traceability.
- **Quality Control Tests:** These include tests for residual solvents, heavy metals, microbial contamination, and physical properties.
- **Post-market Surveillance:** Ongoing monitoring of excipient safety is mandated, particularly as new impurities or adverse effects are identified. This robust regulatory infrastructure ensures that Japanese excipients meet not only domestic safety standards but also align with global expectations, facilitating international trade and cooperation.

--- Manufacturing Practices and Quality Standards in Japan

Japanese pharmaceutical excipient manufacturers are recognized for their meticulous manufacturing practices rooted in advanced technology and quality assurance systems. The key features include:

- **High-Purity Raw Materials:** Suppliers adhere to strict specifications to ensure raw material purity, minimizing impurities that could compromise drug safety.
- **Advanced Manufacturing Technologies:** Many Japanese

companies utilize state-of-the-art equipment such as continuous processing, real-time monitoring, and automation to ensure consistency.

- **Stringent Quality Control:** Comprehensive testing at multiple stages of production, including raw material inspection, in-process checks, and final product testing.
- **Environmental Controls:** Manufacturing facilities operate under strict environmental controls to prevent contamination, aligning with ISO 9001 and other international standards.
- **Traceability:** Robust documentation practices facilitate traceability from raw materials to finished excipients, vital for regulatory audits and safety monitoring.

Japanese excipient manufacturers often collaborate with pharmaceutical companies to customize excipients tailored to specific formulation needs, emphasizing innovation and quality.

--- **Innovations in Japanese Pharmaceutical Excipients**

Japan's pharmaceutical industry is at the forefront of excipient innovation, driven by a combination of technological advances, research investments, and regulatory encouragement. Notable areas of innovation include:

1. **Biocompatible and Natural Excipients** Growing consumer demand for natural and safer excipients has spurred the development of plant-derived, biodegradable, and biocompatible excipients. Examples include cellulose derivatives from sustainably sourced materials and natural gums.
2. **Functional Excipients for Controlled Release** Japanese companies have pioneered excipients that enable precise control over drug release profiles. These include novel polymer matrices and smart coatings responsive to pH or enzymes, enhancing targeted delivery.
3. **Excipient Compatibility with Advanced Delivery Systems** With the rise of nanotechnology and biopharmaceuticals, excipients compatible with liposomes, nanoparticles, and other delivery platforms are being developed. For instance, specialized surfactants and stabilizers tailored for nanocarriers.
4. **Reduced Additive Content** Efforts aim to minimize the use of preservatives and coloring agents, reducing potential adverse reactions, especially in pediatric and geriatric populations.
5. **Sustainability and Eco-Friendly Production** Japanese excipient manufacturers emphasize environmentally sustainable practices, including waste reduction, energy efficiency, and the use of renewable resources.

--- **Impact of Japanese Excipient Standards on Global Pharmaceuticals**

Japan's high standards for pharmaceutical excipients influence global manufacturing practices and regulatory policies. The country's excipients are often considered benchmarks for quality, safety, and innovation. This influence manifests in several ways:

- **Global Supply Chain:** Many Japanese excipients are exported worldwide, often used in formulations approved by regulatory agencies such as the FDA and EMA.
- **Regulatory Harmonization:** Japanese standards frequently align with or complement international guidelines, facilitating smoother approval processes for multinational drug products.
- **Innovation Leadership:** Advances developed in Japan often set trends adopted globally, such as environmentally friendly excipients or advanced controlled-release technologies.
- **Collaborative Research:** Japanese pharmaceutical companies and excipient manufacturers actively collaborate with international partners to develop new formulations and standards. This synergy enhances the overall quality and safety of pharmaceutical products worldwide, contributing to improved patient outcomes.

--- **Challenges and Future Perspectives**

Despite its strengths, the Japanese pharmaceutical excipient industry faces challenges that include:

- **Regulatory Complexity:** Navigating stringent approval processes can delay the introduction of new excipients.
- **Cost of Innovation:** High R&D and manufacturing costs

may limit the pace of innovation. - Global Competition: Increasing competition from emerging markets requires Japanese manufacturers to continuously improve quality and cost-efficiency. Looking ahead, the future of Japanese pharmaceutical excipients is poised for growth driven by: - Personalized Medicine: Development of excipients tailored for individualized therapies. - Biopharmaceuticals: Creation of excipients compatible with biologics and gene therapies. - Sustainable Practices: Further emphasis on eco-friendly manufacturing and biodegradable excipients. - Digital Integration: Adoption of digital technologies for real-time monitoring and quality assurance. Japanese excipient manufacturers are expected to maintain their leadership role by balancing innovation with rigorous safety standards, fostering collaborations, and responding to evolving global healthcare needs. --- Conclusion Japanese pharmaceutical excipients exemplify a commitment to excellence, safety, and innovation within the pharmaceutical landscape. Their diverse types, stringent regulatory oversight, advanced manufacturing practices, and pioneering research collectively contribute to high-quality medicines both domestically and internationally. As the industry progresses toward personalized, sustainable, and technologically advanced therapies, Japanese excipients are well-positioned to continue their influential role in shaping the future of global pharmaceuticals. Their ongoing development and integration into new delivery systems will undoubtedly support the creation of safer, more effective, and patient-centric medications worldwide. Japanese pharmaceutical excipients, pharmaceutical excipients Japan, Japan excipient manufacturers, Japanese pharmaceutical additives, Japan drug excipients, pharmaceutical excipient suppliers Japan, Japan pharmaceutical excipient standards, Japanese excipient formulations, Japan pharmaceutical excipient regulations, Japanese excipient industry

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this book provides an overview of excipients their functionalities in pharmaceutical dosage forms regulation and selection for pharmaceutical products formulation it includes development characterization methodology applications and up to date advances through the perspectives of excipients developers users and regulatory experts covers the sources characterization and harmonization of excipients essential information for optimal excipients selection in pharmaceutical development describes the physico chemical properties and biological effects of excipients discusses chemical classes safety and toxicity and formulation addresses recent efforts in the standardization and harmonization of excipients

provides data on the additives used to convert pharmacologically active compounds into dosage forms suitable for administration to patients data includes nonproprietary names functional category synonyms chemical names and cas registry number empirical formula molecular weight structural formula commercial availability method of manufacture description pharmacopeial specifications typical properties stability and storage conditions incompatibilities safety handling precautions regulatory acceptance applications in pharmaceutical formulation or technology use related substances comments and specific references

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this handbook features contributions from a team of expert authors representing the many disciplines within science engineering and technology that are involved in pharmaceutical manufacturing they provide the information and tools you need to design implement operate and troubleshoot a pharmaceutical manufacturing system the editor with more than thirty years experience working with pharmaceutical and biotechnology companies carefully reviewed all the chapters to ensure that each one is thorough accurate and clear

to facilitate the development of novel drug delivery systems and biotechnology oriented drugs the need for new yet to be developed and approved excipients continues to increase excipient development for pharmaceutical biotechnology and drug delivery systems serves as a comprehensive source to improve understanding of excipients and forge potential new avenues for regulatory approval this book presents detailed up to date information on various aspects of excipient development testing and technological considerations for their use it addresses specific details such as historical perspective preclinical testing safety and toxicology evaluation as well as regulatory quality and utility aspects the text also describes best practices for use of various functional excipients and extensive literature references for all topics

with global harmonization of regulatory requirements and quality standards and national and global business consolidations ongoing at a fast pace pharmaceutical manufacturers suppliers contractors and distributors are impacted by continual change offering a wide assortment of policy and guidance document references and interpretations this sixth edition is significantly expanded to reflect the increase of information and changing practices in cgmpr regulation and pharmaceutical manufacturing and control practices worldwide an essential companion for every pharmaceutical professional this guide is updated and expanded by a team of industry experts each member with extensive experience in industry or academic settings

this is the second edition of a work on pharmaceutical excipients it has been expanded and revised to include 203 monographs for pharmacopoeial and non pharmacopoeial excipients the appendices include a substantial suppliers directory all the physical properties of excipients are included

describes the chemical and physical properties of pharmaceutical excipients each monograph contains nonproprietary names synonyms chemical name and cas registry number empirical formula and molecular weight structural formula functional category applications in pharmaceutical formulation or technology description pharmacopeial specifications typical properties stability and storage conditions incompatibilities method of manufacture safety handling precautions regulatory status pharmacopeias related substances comments specific references general references and authors

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in recent years emerging trends in the design and development of drug products have indicated ever greater need for integrated characterization of excipients and in depth understanding of their roles in drug delivery applications this book presents a concise



summary of relevant scientific and mechanistic information that can aid the use of excipients in formulation design and drug delivery applications each chapter is contributed by chosen experts in their respective fields which affords truly in depth perspective into a spectrum of excipient focused topics this book captures current subjects of interest with the most up to date research updates in the field of pharmaceutical excipients this includes areas of interest to the biopharmaceutical industry users students educators excipient manufacturers and regulatory bodies alike

an internationally acclaimed reference work recognized as one of the most authoritative and comprehensive sources of information on excipients used in pharmaceutical formulation with this new edition providing 340 excipient monographs incorporates information on the uses and chemical and physical properties of excipients systematically collated from a variety of international sources including pharmacopeias patents primary and secondary literature websites and manufacturers data extensive data provided on the applications licensing and safety of excipients comprehensively cross referenced and indexed with many additional excipients described as related substances and an international supplier s directory and detailed information on trade names and specific grades or types of excipients commercially available

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this book will provide a useful introduction for those relatively unfamiliar with this highly technical subject as it gives broad coverage of a very diverse area

meeting the need for a hands on guide elucidating the role of molecular spectroscopy in the physical characterization of pharmaceutical solids two experts from the industry gather theoretical discussions of infrared raman and nuclear magnetic resonance spectroscopy they provide recommendations on spectral data acquisition techniques and include 600 spectra for 300 of the most commonly used excipients complete with references equations tables and a cas registry number index the book covers the drug development process including chemical identification of substances investigative studies competitor analysis problem solving activities reproduction of spectral data and more

plant polysaccharides as pharmaceutical excipients explores innovative techniques and applications of plant derived polysaccharides as pharmaceutical excipients plant polysaccharides are sustainable renewable and abundantly available offering attractive

properties in terms of water solubility swelling ability non toxicity and biodegradability these qualities have resulted in extensive exploration into their applications as excipients in a variety of pharmaceutical dosage forms this book takes a comprehensive application oriented approach drawing on the very latest research that includes sources classification and extraction methods of plant polysaccharides subsequent chapters focus on plant polysaccharides for individual pharmaceutical applications enabling the reader to understand their preparation for specific targeted uses throughout the book information is supported by illustrations chemical structures flow charts and data tables providing a clear understanding finally future perspectives and challenges are reviewed and discussed explains sources classifications extraction methods and biocompatibility of plant polysaccharides guides the reader through properties and preparation methods of plant polysaccharides as pharmaceutical excipients covers a broad range of cutting edge applications with each chapter targeting a specific use

doctoral thesis dissertation from the year 2022 in the subject chemistry other language english abstract the title of this thesis synthesis and characterization of drug carrier based on polysaccharides clearly reflects the objective which is an approach towards preparation of excipients defined as the substance used as a medium for giving a medicament that is to say with simply the functions of an inert support of the active principle or principles okra gum obtained from the fruits of hibiscus esculents is a polysaccharide consisting of d galactose l rhamnose and l galacturonic acid it is used as a binder in studies okra gum has been evaluated as a binder in paracetamol tablet formulations these formulations containing okra gum as a binder showed a faster onset and higher amount of plastic deformation than those containing gelatin the crushing strength and disintegration times of the tablets increased with higher binder concentration while their friability decreased although gelatin produced four tablets with higher crushing strength okra gum produced tablets with longer disintegration times than those containing gelatin it was finally concluded from the results that okra gum may be a useful hydrophilic matrixing agent in sustained drug delivery system various strategies were developed in order to overcome these issues offering the opportunity to tailor the physical and chemical properties of okra gum thus yielding materials that may find a wide range of applications extraction and purification of okra gum was carried out from okra pods followed by carboxymethylated and phosphorylation of extracted okra gum which was carried out along with optimization of reaction parameter of the primary derivatives that is carboxymethylated okra gum and hydroxyl propyl okra phosphate followed by drug carriers preparation by the second modification carboxymethylated okra gum and hydroxyl propyl okra phosphate were carried out by cross linking acrylic acid n n methylene acryl amide hydroxyethyl methacrylate hema respectively synthesized cross linked polymer were further investigated as drug carriers by formulating as tablet for sustained drug release the drug release of different formulations were measured in relation to time and also compared with the standard drugs further mathematical modeling was implemented to know the order of release behavior of formulated tables

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